AMENDED IN SENATE APRIL 23, 2014 AMENDED IN SENATE MARCH 25, 2014

SENATE BILL

No. 1258

Introduced by Senator DeSaulnier

February 21, 2014

An act to amend Sections 4071 and 4072 of the Business and Professions Code, and to amend Sections 11151, 11158, 11164, 11164.1, 11164.5, 11165, 11165.1, 11165.5, 11166, and 11200 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

- SB 1258, as amended, DeSaulnier. Controlled substances: prescriptions: reporting.
- (1) Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances. Existing law requires specified information regarding prescriptions for Schedule II, Schedule III, and Schedule IV controlled substances, including the ultimate user of the prescribed controlled substance and the National Drug-Control Code number of the controlled substance dispensed, to be reported to the Department of Justice.

This bill would additionally require the prescribing and dispensing of Schedule V controlled substances to be monitored in CURES and would require specified information regarding prescriptions for Schedule V controlled substances to be reported to the Department of Justice.

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(2) Existing law requires licensed health care practitioners, as specified, and pharmacists to apply to the Department of Justice to obtain approval to access information contained in the CURES Prescription Drug Monitoring—System Program (PDMP) regarding the controlled substance history of a patient under his or her care. Existing law requires the Department of Justice, upon approval of that application, to provide to that health care practitioner or pharmacist the history of controlled substances dispensed to an individual under his or her care.

This bill would also authorize an individual designated to investigate an applicant for, or a holder of, of a professional license to apply to the Department of Justice to obtain approval to access information contained in the CURES PDMP regarding the controlled substance history of an applicant or a licensee for the purpose of investigating the alleged substance abuse of an applicant or a licensee. The bill would, upon approval of that application, require the department to provide to that individual the history of controlled substances dispensed to the applicant or licensee.

(3) Existing law generally requires, subject to specified exceptions, that a prescription for Schedule II, Schedule III, Schedule IV, or Schedule V controlled substances be made on a certain controlled substance prescription form and meet several requirements, including that the prescription be signed and dated by the prescriber in ink. Existing law authorizes, as an exception to that requirement, a Schedule III, Schedule IV, or Schedule V controlled substance to be dispensed upon an oral or electronically transmitted prescription, which must be produced in hard copy form and signed and dated by the pharmacist filling the prescription or another authorized person.

This bill would instead require, subject to specified exceptions, commencing January 1, 2016, that a prescription for a controlled substance be made by an electronically transmitted prescription that complies with regulations promulgated by the Drug Enforcement Agency, which, except as specified, must be produced in hard copy form and signed and dated by the pharmacist filling the prescription or another authorized person. The bill would provide that those requirements apply to medical practices with 2 or fewer physicians and medical providers in underserved rural areas commencing January 1, 2017.

(4) Existing law prohibits a prescription for a Schedule II controlled substance from being refilled and prohibits a prescription for a Schedule

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III or IV controlled substance from being refilled more than 5 times and in an amount, for all refills of that prescription taken together, exceeding a 120-day supply.

This bill would prohibit, subject to specified exceptions, a person from prescribing a controlled substance, or filling, compounding, or dispensing a prescription for a controlled substance, in a quantity exceeding a 30 day 30-day supply. The bill would also prohibit a person from issuing a prescription for a controlled substance, or from filling, compounding, or dispensing a prescription for a controlled substance, for an ultimate user for whom a previous prescription for-a that controlled substance was issued within the immediately preceding 30 days until the ultimate user has exhausted all but a 7-day supply of the that controlled substance filled, compounded, or dispensed from the previous prescription.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

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The people of the State of California do enact as follows:

SECTION 1. Section 4071 of the Business and Professions 1 Code is amended to read:

4071. Notwithstanding any other provision of law, a prescriber may authorize his or her agent on his or her behalf to orally or electronically transmit a prescription to the furnisher. The furnisher shall make a reasonable effort to determine whether the person who transmits the prescription is authorized to do so and shall record the name of the authorized agent of the prescriber who transmits the order.

SEC. 2. Section 4072 of the Business and Professions Code is 10 amended to read:

4072. (a) Notwithstanding any other law, a pharmacist, registered nurse, licensed vocational nurse, licensed psychiatric technician, or other healing arts licentiate, if so authorized by administrative regulation, who is employed by or serves as a consultant for a licensed skilled nursing, intermediate care, or other health care facility, may orally or electronically transmit to the furnisher a prescription lawfully ordered by a person authorized to prescribe drugs or devices pursuant to Sections 4040 and 4070. The furnisher shall take appropriate steps to determine whether the person who transmits the prescription is authorized to do so

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and shall record the name of the person who transmits the order.
This section does not apply to oral orders for Schedule II controlled
substances.

- (b) In enacting this section, the Legislature recognizes and affirms the role of the State Department of Public Health in regulating drug order processing requirements for licensed health care facilities as set forth in Title 22 of the California Code of Regulations as they may be amended from time to time.
- SEC. 3. Section 11151 of the Health and Safety Code is amended to read:
- 11151. A prescription issued by an unlicensed person lawfully practicing medicine pursuant to Section 2065 of the Business and Professions Code, shall be filled only at a pharmacy maintained in the hospital which employs such that unlicensed person.
- SEC. 4. Section 11158 of the Health and Safety Code is amended to read:
- 11158. (a) Except as provided in Section 11159, 11159.1, 11159.2, 11167, or 11167.5, or in subdivision (b) of this section, a controlled substance classified in Schedule II shall not be dispensed without a prescription meeting the requirements of this chapter. Except as provided in Section 11159, 11159.1, 11159.2, 11167, or 11167.5, or when dispensed directly to an ultimate user by a practitioner, other than a pharmacist or pharmacy, a controlled substance classified in Schedule III, IV, or V shall not be dispensed without a prescription meeting the requirements of this chapter.
- (b) A practitioner specified in Section 11150 may dispense directly to an ultimate user a controlled substance classified in Schedule II in an amount not to exceed a 72-hour supply for the patient in accordance with directions for use given by the dispensing practitioner only if the patient is not expected to require any additional amount of the controlled substance beyond the 72 hours.
- (c) Except as otherwise prohibited or limited by law, a practitioner specified in Section 11150, may administer controlled substances in the regular practice of his or her profession.
- 36 SEC. 5. Section 11164 of the Health and Safety Code is amended to read:
- 38 11164. Except as provided in Section 11158, 11159, 11159.1, 39 11159.2, 11167, or 11167.5, a person shall not prescribe a 40 controlled substance, nor shall any person fill, compound, or

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dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

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- (a) (1) A—(A) Except as provided in subparagraph (B), commencing January 1, 2016, a prescription for a controlled substance classified in Schedule II, III, IV, or V shall be made by an electronically transmitted prescription that complies with regulations promulgated by the *United States* Drug Enforcement Agency Administration, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiality of the prescription.
- (B) For medical practices with two or fewer physicians, and for medical providers in underserved rural areas, the requirements in subparagraph (A) shall apply commencing January 1, 2017.
- (2) A prescription issued pursuant to this subdivision shall meet the following requirements:
- (A) The prescription shall contain the prescriber's address and telephone number; the name of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services; refill information, such as the number of refills ordered and whether the prescription is a first-time request or a refill; and the name, quantity, strength, and directions for use of the controlled substance prescribed.
- (B) The prescription shall contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall include the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.
- (3) Pursuant to an authorization of the prescriber, an agent of the prescriber on behalf of the prescriber may electronically transmit a prescription for a controlled substance classified in Schedule II, III, IV, or V, if the prescription specifies the name of the agent of the prescriber transmitting the prescription.
- 39 (b) (1) A prescription for a controlled substance classified in 40 Schedule II, III, IV, or V, may be written on a controlled substance

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prescription form as specified in Section 11162.1, or for a controlled substance classified in Schedule III, IV, or V, may be made orally, if technological failure prevents the electronic transmission of a prescription pursuant to subdivision (a) or if the prescription will be filled by a pharmacist located outside of California, provided that the order contains all information required by subdivision (a) and, if the prescription is written on a controlled substance prescription form, is signed and dated by the prescriber in ink.

- (2) If a prescriber is permitted to make an oral prescription pursuant to this section, pursuant to an authorization of the prescriber, an agent of the prescriber on behalf of the prescriber may orally transmit a prescription for a controlled substance classified in Schedule II, III, IV, or V, if the written record of the prescription specifies the name of the agent of the prescriber transmitting the prescription.
- (c) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.
- (d) Notwithstanding any provision of subdivisions (a) and (b), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.
- SEC. 6. Section 11164.1 of the Health and Safety Code is amended to read:
- 11164.1. (a) (1) Notwithstanding any other law, a prescription for a controlled substance issued by a prescriber in another state for delivery to a patient in another state may be dispensed by a California pharmacy, if the prescription conforms with the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed.
- (2) All prescriptions for Schedule II, Schedule III, Schedule IV, and Schedule V controlled substances dispensed pursuant to this subdivision shall be reported by the dispensing pharmacy to the Department of Justice in the manner prescribed by subdivision (d) of Section 11165.
- (b) Pharmacies may dispense prescriptions for Schedule III, Schedule IV, and Schedule V controlled substances from out-of-state prescribers pursuant to Section 4005 of the Business and Professions Code and Section 1717 of Title 16 of the California Code of Regulations.

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SEC. 7. Section 11164.5 of the Health and Safety Code is amended to read:

- 11164.5. (a) A pharmacy or hospital shall receive electronic data transmission prescriptions or computer entry prescriptions or orders as specified in Section 4071.1 of the Business and Professions Code, for controlled substances in Schedule II, III, IV, or V in accordance with regulations promulgated by the *United States* Drug Enforcement Administration.
- (b) Notwithstanding paragraph (1) of subdivision (a) of Section 11164, a pharmacy or hospital receiving an electronic transmission prescription or a computer entry prescription or order for a controlled substance classified in Schedule II, III, IV, or V is not required to reduce that prescription or order to writing or to hard copy form, if for three years from the last day of dispensing that prescription, the pharmacy or hospital is able, upon request of the board or the Department of Justice, to immediately produce a hard copy report that includes for each date of dispensing of a controlled substance in Schedules II, III, IV, and V pursuant to the prescription all of the information described in subparagraphs (A) to (E), inclusive, of paragraph (1) of subdivision (a) of Section 4040 of the Business and Professions Code and the name or identifier of the pharmacist who dispensed the controlled substance.
- (c) If only recorded and stored electronically, on magnetic media, or in any other computerized form, the pharmacy's or hospital's computer system shall not permit the received information or the controlled substance dispensing information required by this section to be changed, obliterated, destroyed, or disposed of, for the record maintenance period required by law, once the information has been received by the pharmacy or the hospital and once the controlled substance has been dispensed, respectively. Once the controlled substance has been dispensed, if the previously created record is determined to be incorrect, a correcting addition may be made only by or with the approval of a pharmacist. After a pharmacist enters the change or enters his or her approval of the change into the computer, the resulting record shall include the correcting addition and the date it was made to the record, the identity of the person or pharmacist making the correction, and the identity of the pharmacist approving the correction.

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(d) Nothing in this section shall be construed to exempt any pharmacy or hospital dispensing Schedule II controlled substances pursuant to electronic transmission prescriptions from existing reporting requirements.

- SEC. 8. Section 11165 of the Health and Safety Code is amended to read:
- 11165. (a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, Schedule IV, and Schedule V controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, Schedule IV, and Schedule V controlled substances by all practitioners authorized to prescribe, order, administer, furnish, or dispense these controlled substances.
- (b) The Department of Justice may seek and use grant funds to pay the costs incurred by the operation and maintenance of CURES. The department shall annually report to the Legislature and make available to the public the amount and source of funds it receives for the support of CURES.
- (c) (1) The operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations.
- (2) CURES shall operate under existing law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to an individual or agency as described in this subdivision

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shall not be disclosed, sold, or transferred to a third party. The Department of Justice shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with this subdivision.

- (d) For each prescription for a Schedule II, Schedule III, Schedule IV, or Schedule V controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, 1308.14, and 1308.15, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:
- (1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.
- (2) The prescriber's category of licensure, license number, national provider identifier National Provider Identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
- (3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.
- (4) National Drug Code (NDC) number of the controlled substance dispensed.
 - (5) Quantity of the controlled substance dispensed.
- (6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.
 - (7) Number of refills ordered.

- (8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.
- (9) Date of origin of the prescription.
 - (10) Date of dispensing of the prescription.
- 39 (e) The Department of Justice may invite stakeholders to assist, 40 advise, and make recommendations on the establishment of rules

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and regulations necessary to ensure the proper administration and enforcement of the CURES database. All prescriber and dispenser invitees shall be licensed by one of the boards or committees dentified in subdivision (d) of Section 208 of the Business and Professions Code, in active practice in California, and a regular user of CURES.

- (f) The Department of Justice shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, one or more of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, and any other stakeholder identified by the department, for the purpose of identifying desirable capabilities and upgrades to the CURES Prescription Drug Monitoring Program (PDMP).
- (g) The Department of Justice may establish a process to educate authorized subscribers of the CURES PDMP on how to access and use the CURES PDMP.
- SEC. 9. Section 11165.1 of the Health and Safety Code is amended to read:
- 11165.1. (a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, Schedule IV, or Schedule V controlled substances pursuant to Section 11150 shall, before January 1, 2016, or upon receipt of a federal Drug Enforcement Administration (DEA) registration, whichever occurs later, submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained within the Department of Justice, and, upon approval, the department shall release to that practitioner the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).
- (ii) A pharmacist shall, before January 1, 2016, or upon licensure, whichever occurs later, submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained within the Department of Justice, and, upon approval, the department shall

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release to that pharmacist the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES PDMP.

- (iii) An individual designated by a board, bureau, or program within the Department of Consumer Affairs to investigate—an applicant for, or a holder of, a professional license may, for the purpose of investigating the alleged substance abuse of an applicant or a licensee, submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled substance history of an applicant or a licensee that is stored on the Internet and maintained within the Department of Justice, and, upon approval, the department shall release to that individual the electronic history of controlled substances dispensed to the applicant or licensee based on data contained in the CURES PDMP. The application shall contain facts demonstrating the probable cause to believe the licensee has violated a law governing controlled substances.
- (B) An application may be denied, or a subscriber may be suspended, for reasons which include, but are not limited to, the following:
 - (i) Materially falsifying an application for a subscriber.
- (ii) Failure to maintain effective controls for access to the patient activity report.
 - (iii) Suspended or revoked federal DEA registration.
- (iv) Any subscriber who is arrested for a violation of law governing controlled substances or any other law for which the possession or use of a controlled substance is an element of the crime.
- (v) Any subscriber accessing information for any other reason than caring for his or her patients.
- (C) Any authorized subscriber shall notify the Department of Justice within 30 days of any changes to the subscriber account.
- (2) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, Schedule IV, or Schedule V controlled substances pursuant to Section 11150 or a pharmacist shall be deemed to have complied with paragraph (1) if the licensed health care practitioner or pharmacist has been approved to access the CURES database through the process developed pursuant to subdivision (a) of Section 209 of the
- 40 Business and Professions Code.

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(b) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.

- (c) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, Schedule IV, or Schedule V controlled substances, the Department of Justice may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.
- (d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by an authorized subscriber from the Department of Justice pursuant to this section shall be considered medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.
- (e) Information concerning a patient's controlled substance history provided to an authorized subscriber pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, 1308.14, and 1308.15 of Title 21 of the Code of Federal Regulations.
- SEC. 10. Section 11165.5 of the Health and Safety Code is amended to read:
- 11165.5. (a) The Department of Justice may seek voluntarily contributed private funds from insurers, health care service plans, qualified manufacturers, and other donors for the purpose of supporting CURES. Insurers, health care service plans, qualified manufacturers, and other donors may contribute by submitting their payment to the Controller for deposit into the CURES Fund established pursuant to subdivision (c) of Section 208 of the Business and Professions Code. The department shall make information about the amount and the source of all private funds it receives for support of CURES available to the public. Contributions to the CURES Fund pursuant to this subdivision shall be nondeductible for state tax purposes.
 - (b) For purposes of this section, the following definitions apply:
- (1) "Controlled substance" means a drug, substance, or immediate precursor listed in any schedule in Section 11055, 11056, 11057, or 11058 of the Health and Safety Code.

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(2) "Health care service plan" means an entity licensed pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

- (3) "Insurer" means an admitted insurer writing health insurance, as defined in Section 106 of the Insurance Code, and an admitted insurer writing workers' compensation insurance, as defined in Section 109 of the Insurance Code.
- (4) "Qualified manufacturer" means a manufacturer of a controlled substance, but does not mean a wholesaler or nonresident wholesaler of dangerous drugs, regulated pursuant to Article 11 (commencing with Section 4160) of Chapter 9 of Division 2 of the Business and Professions Code, a veterinary food-animal drug retailer, regulated pursuant to Article 15 (commencing with Section 4196) of Chapter 9 of Division 2 of the Business and Professions Code, or an individual regulated by the Medical Board of California, the Dental Board of California, the California State Board of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Committee of the Medical Board of California, the Osteopathic Medical Board of California, the State Board of Optometry, or the California Board of Podiatric Medicine.
- SEC. 11. Section 11166 of the Health and Safety Code is amended to read:
- 11166. A person shall not fill a prescription for a controlled substance after six months has elapsed from the date the prescription was issued by the prescriber. A person shall not knowingly fill a mutilated or forged or altered prescription for a controlled substance except for the addition of the address of the person for whom the controlled substance is prescribed as provided by paragraph (2) of subdivision (b) of Section 11164.
- SEC. 12. Section 11200 of the Health and Safety Code is amended to read:
- 11200. (a) A person shall not dispense or refill a controlled substance prescription more than six months after the date thereof.
- (b) (1) Except as provided in paragraph (2), a person shall not prescribe a controlled substance, nor shall a person fill, compound, or dispense a prescription for a controlled substance, in a quantity exceeding a 30-day supply.

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(2) A person may prescribe a controlled substance, and a person may fill, compound, or dispense a prescription for a controlled substance, in a quantity not exceeding a 90-day supply if the prescription is issued in the treatment of one of the following:

(A) A panic disorder.

- (B) Attention deficit disorder.
- (C) A chronic debilitating neurologic condition characterized as a movement disorder or exhibiting seizure, convulsive, or spasm activity.
- (D) Pain in patients with conditions or diseases known to be chronic or incurable.
 - (E) Narcolepsy.
- (F) Any other condition or circumstance for which the physician determines is a medical necessity, provided the reason for the medical necessity is noted in the prescription and in the patient's medical record.
- (c) (1) A prescription for a Schedule III or IV substance shall not be refilled more than five times and in an amount, for all refills of that prescription taken together, exceeding a 120-day supply.
- (2) A prescription for a Schedule II substance shall not be refilled.
- (d) A person shall not issue a prescription for a controlled substance, nor shall a person fill, compound, or dispense a prescription for a controlled substance, for an ultimate user for whom a previous prescription for-a that controlled substance was issued within the immediately preceding 30 days until the ultimate user has exhausted all but a seven-day supply of-the that controlled substance filled, compounded, or dispensed from the previous prescription. This subdivision does not prohibit an ultimate user from being issued multiple prescriptions, each for a different controlled substance, at a given time.